UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,781	10/10/2001	Michael G. Kahn	FSTK 1004-1	8124

22470 7590 08/16/2006

HAYNES BEFFEL & WOLFELD LLP
P O BOX 366
HALF MOON BAY, CA 94019

EXAMINER	
COBANOGLU, DILEK B	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/974,781	KAHN ET AL.	
	Examiner	Art Unit	
	Dilek B. Cobanoglu	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/2002,4/17/2006*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the amendment filed 04/17/2006. Claims 1-51 continue pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

A. The 35 U.S.C. 112, second paragraph rejection of claims 39 and 41 have been withdrawn as a result of Applicant's amendments received on 04/17/2006.

B. The amended claims 1, 10, 42 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amended claims disclose "...said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter too vaguely to be encoded into said database, or said protocol specification specifies such a parameter inconsistently". The limits of the parameter to be too vaguely, is not clear on these claims. Also, the limits of the parameter be inconsistent is not clear on these claims. There are no specific and clear limits of the real values or parameters on these claims; therefore they are rejected under 35 U.S.C. 112, second paragraph for being indefinite.

C. The amended claims 1 and 42 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amended claims disclose "...encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trail protocol, an indication that said operational uncertainty exists with respect to said particular object". Claim 1 and 42 recites the limitation " an indication that said operational uncertainty exists " in clinical trail protocol. There is insufficient antecedent basis for this limitation in the claim. Therefore claims 1 and 42 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-9, 42-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (U.S. Patent No. 6,196,970) and Friedman (U.S. Patent No. 6,055,494) as stated in the previous office action and further in view of Herren et al. (hereinafter Herren) (U.S. Patent No. 6,108,635).

A. Claim 1 has been amended now to disclose a method for evaluating a clinical trial protocol specification, comprising the steps of:

i. encoding into a database, workflow tasks called for in a clinical trial protocol specification, including the step of encoding, into protocol specification objects of said database, specifications of protocol events that said protocol specifies to occur during execution of said protocol, and further including the step of encoding, into protocol specification objects of said database, relationships that said protocol specifies among said protocol events (Brown; col. 3, line 66 to col. 4, line 3 and col. 6, lines 43-45).

ii. Encoding into said database in association with at least a particular one of said protocol specification objects in said database, an indication that said operational uncertainty exists wit respect to said particular object (Brown; col. 4, lines 15-17);

iii. In dependence upon protocol specification objects in said database displaying a graphical-visual representation of said protocol (Brown; col. 6, lines 19-23).

Brown fails to expressly teach the encoding workflow tasks into a database not yet in execution and identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or

said protocol specification specifies such a parameter too vaguely to be encoded into said database, or said protocol specification specifies such a parameter inconsistently, per se, since it appears that Brown is more directed to collecting and analyzing research data during the course of the research testing and presenting subjects narrowly structured questions to identify uncertainties during the course of the research testing. However, this feature is well known in the art, as evidenced by Herren.

In particular, Herren discloses encoding workflow tasks into a database not yet in execution and identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter too vaguely to be encoded into said database, or said protocol specification specifies such a parameter inconsistently (Herren; col. 5, line 45-col. 6, line 7).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Herren with the motivation of determining the impact of various clinical trial designs prior to actual implementation of

clinical trial and determining the likelihood of useful results (Herren; col. 5, lines 62-65).

The obviousness of modifying the teaching of Brown and Herren to include a human-perseptible indication (as taught by Freidman) is as addressed in the previous office action mailed on 10/18/2005 and incorporated herein.

A. Claim 42 has been amended to disclose the same scope of limitations as claim 1; therefore is rejected with the same limitations of rejection of claim 1 as described above and incorporated herein.

B. Claims 45-47 have not been amended, and claims 43, 44, 48-51 have been amended for minor corrections. Therefore the scopes of these claims remain the same and they are rejected with the same reasons given in the previous office action and incorporated herein.

5. Claim 2 has not been amended, and claims 3-9 have been amended for minor corrections. Therefore the scopes of these claims remain the same and they are rejected with the same reasons given in the previous office action and incorporated herein.

6. Claims 10 to 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (U.S. Patent No. 6,196,970) and Cunningham (U.S Patent No. 5,832,449) as stated in the previous office action and further in view of Herren et al. (hereinafter Herren) (U.S. Patent No. 6,108,635).

A. Claim 10 has been amended now to disclose a set of at least one computer readable medium said set carrying a machine readable database which includes protocol specification objects describing protocol events that a protocol specification specifies to occur during execution of said protocol, and relationships among said protocol events

The obviousness of modifying the teaching of Brown to include computer readable medium (as taught by Cunningham) is as addressed in the previous office action mailed on 10/18/2005 and incorporated herein.

The obviousness of modifying the teaching of Brown and Cunningham to include protocol specification specifies to occur during execution of said protocol (as taught by Herren) is as addressed above in the rejection of claim 1 and incorporated herein.

B. Claims 11, 13-15, 17-18, 22, 27-29 have not been amended, and claims 12, 16, 19-21, 24-26 and 30-33 have been amended for minor corrections. Therefore the scope of this claims remain the same and it is rejected with the same reasons given in the previous office action and incorporated herein.

C. Claim 23 has been amended now to disclose a set of at least one computer readable medium the set carrying a plurality of machine readable objects instantiated according to a pre-specified class structure, the machine readable objects including protocol event specification objects describing protocol events that a protocol specification specifies to occur during execution of said protocol, and temporal constraint specification objects describing temporal relationships

that a protocol specification specifies to occur among protocol events described in said protocol event specification objects, at least a particular one of said temporal constraint specification objects identifying an amount of time that said protocol specifies is to elapse between two or more protocol events when the protocol is executed. (Brown; col.3, line 66 to col. 4, line 19 and col. 3, lines 49-60)

The obviousness of modifying the teaching of Brown to include the computer readable medium (as taught by Cunningham) is as addressed in the previous office action and incorporated herein.

7. Claims 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (U.S. Patent No. 6,196,970), Friedman (U.S. Patent No. 6,055,494) and Cunningham (U.S Patent No. 5,832,449) and further in view of Herren et al. (hereinafter Herren) (U.S. Patent No. 6,108,635).

A. The amended claim 34 disclose the same limitations of claim 23 and claim 1 (ii); therefore claim 34 is rejected with the same reasons given above for the rejections of claims 23 and 1, and incorporated herein.

A. Claim 35 has not been amended, and claims 36-41 have been amended for minor corrections. Therefore the scopes of these claims remain the same and they are rejected with the same reasons given in the previous office action and incorporated herein.

Response to Arguments

8. Applicant's arguments with respect to claims 1-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBC
Art Unit 3626
06/22/2006

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER